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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,381	07/11/2001	Charles W. Hewitt	266/156	8315

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/27/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,381

Applicant(s)

HEWITT, CHARLES W.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-22 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 17, 18, 20-22, 26-29 is/are rejected.
- 7) ☒ Claim(s) 16 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13, 15-22, 26-29 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims are limited to “naturally occurring tissue” while claims 26-29 attempt to expand the scope of the independent claims by reciting “naturally occurring tissue or a bioartificially constructed tissue”.

Claim Rejections – 35 USC § 102

Claims 26-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Doolin *et al.* [AL].

The claims are directed to a composition comprising two segments of a bioartificially constructed tissue, one of which has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis and the other is a negative control.

Doolin *et al.* disclose living skin equivalent which has been reproducibly thermally injured. Thermal injury to LSE tissue induces measurable apoptosis. Control segments have not been thermally injured, thus claim 15 is anticipated by the disclosure of CON and BCON, which are two tissue segments.

Claim Rejections – 35 USC § 103

Claims 1-13, 17, 18, 20-22, 26-29 are rejected under 35 U.S.C. 103 as being obvious over Doolin *et al.* [AL] and Lee [U].

The claims are directed to a composition with the intended use of being apoptosis standards. The composition comprises a naturally occurring tissue

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that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis. The composition as claimed need only be a tissue that has undergone a stressor that induces apoptosis. Practically all levels of induced apoptosis are measurable by well known, commercially obtainable means. If one treats a similar piece of tissue to the same stressor, one would reasonably expect to induce the same amount of apoptosis.

Please note that these are not method claims, nor are they product by process claims, they are claims merely to a piece of tissue that has been traumatized in some reproducible manner so as to induce apoptosis. The limitations of claims 2-14 simply describe either inherent properties of the tissue or attempt to introduce process claims into a product claim. It does not matter how the product is produced, merely that it would have the same characteristics as the prior art product.

Doolin *et al.* disclose living skin equivalent which has been reproducibly thermally injured. Thermal injury to LSE tissue induces measurable apoptosis. Control segments have not been thermally injured, thus claim 15 is anticipated by the disclosure of CON and BCON, which are two tissue segments.

Lee is a review article which discloses that living skin equivalents and skin tissue are closely matched in their histological and functional properties (abstract).

The substitution of skin for LSE in the composition of Doolin *et al.* would have been obvious particularly because Lee disclose that skin and living skin equivalents are substantially comparable in their properties and Doolin *et al.* use living skin equivalents in their method in order to avoid the use of animals to obtain skin (p. 375, first paragraph) and the teaching of Doolin *et al.* that the living skin model reacts the same as skin to thermal injury which produces measurable apoptosis.

Further, with regard to claim 17, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947). ("Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.").

Allowable Subject Matter

Claims 16 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants argue that Doolin *et al.* [AL] does not anticipate the claims as it teaches LSE not naturally occurring tissue. This argument is persuasive and the anticipatory rejection over Doolin *et al.* directed to claims stipulating naturally occurring tissue has been removed.

Conclusion

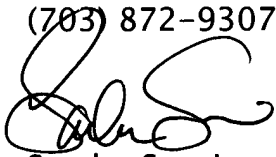
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is written over the printed name.

Sandra Saucier
Primary Examiner
Art Unit 1651
October 22, 2003